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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,930	03/22/2004	Sergey Anatolievich Lukyanov	CLON-094	2888
41064	7590	12/23/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS (BD BIOSCIENCES)			MONDESI, ROBERT B	
1900 UNIVERSITY AVENUE			ART UNIT	
SUITE 200			PAPER NUMBER	
EAST PALO ALTO, CA 94303			1653	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,930	LUKYANOV, SERGEY ANATOLIEVICH	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 4, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 17-26 is/are rejected.
- 7) ☒ Claim(s) 3-5, 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the amendment filed October 05, 2004.

Claims 11-15 are canceled. **Claims 18-26** are new. **Claims 1-10 and 16-26** are currently pending. **Claim 16** is withdrawn. **Claims 1-10 and 17-26** are presently under examination.

Withdrawal of Objections and Rejections

The rejection of **claims 1-10 and 17** under 35 U.S.C § 112, second paragraph is withdrawn.

The rejection of **claims 1-10 and 17** under 35 U.S.C § 101 as being drawn to non-statutory subject matter is withdrawn.

The rejection of **claims 1-10 and 17** under 35 U.S.C. 102(b) as being anticipated by Ward et al. WO 01/32688 is withdrawn.

Response to applicant's arguments

In regards to the priority of the present application, the applicants assert that the present application is entitled to its priority date of October 12, 2001 in regards to the elected subject matter.

In response the examiner would like to state that only certain aspects of the present application are supported by previous provisional and non-provisional disclosures. The provisional applications 60/356,225, 60/383,336 and the non-provisional application 09/976,673 provide support for nucleic acid molecules encoding a polypeptide product comprising a first and second chromo/fluorescent domain;

however the mentioned priority documents do not provide support for nucleic acid molecules encoding a polypeptide product comprising a first and second chromo/fluorescent domain that are from Cnidarian species, e.g., Anthozoan species. The claims that cite nucleic acid molecules encoding a polypeptide product comprising a first and second chromo/fluorescent domain that are from Cnidarian species, e.g., Anthozoan species are only supported in PCT/US02/325060 which has an effective filing date of October 10, 2002. Therefore the priority date for the mentioned subject matter is October 10, 2002.

New rejection(s) and Objection(s)

Specification

The disclosure is objected to because of the following informalities: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below: Nucleic acid sequences longer than 10 nucleotides and amino acid sequences longer than 4 residues need to be designated with a sequence identifier. Applicants must correct the sequence submissions in the specification on: Page 9, line 10.

Claim Objections

Claims 3-5, 19-21 objected to because of the following informalities:

Claims 3-5, 19-21 objected to because the species/family name in the claims is not italicized, for example *Cnidarian*.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In **claims 3-4 and 19-21** the applicants cite nucleic acid molecules that encode a polypeptide product comprising a first and second chromo/fluorescent domain, wherein said chromo/fluorescent are chromo-or fluorescent proteins from a Cnidarian species or mutants; however the applicants have failed to adequately describe the nature of the mentioned mutations. A person skilled in the art would not be able to ascertain whether these mutations are deletions, point mutations or insertions. A person skill in the art would also not to be able to know the appropriate nucleotide position of the presently stated mutations as cited in the claims and specification of the present application. In order to show to a person skill in the art that the applicants had possession of the invention at the time of filing of the present application, the applicants need to provide written description of the nature of the mutations with respect to the mutated nucleotide and its position in the nucleic acid sequence.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116), As discussed above, the skilled artisan cannot envision the detailed chemical structure of all the encompassed nucleic acid mutations, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only nucleic acid molecules that encode a polypeptide product comprising a first and second chromo/fluorescent domain, wherein said chromo/fluorescent are chromo-or fluorescent proteins from a Cnidarian species, but not the full breadth of the claim meets the written description provision of 35 U. S.C. 112, first paragraph. Applicant is reminded that *Vas-cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 17-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/27150.

WO 01/27150 discloses nucleic acid compositions encoding Anthozoa chromo- and fluoroproteins. WO 01/27150 states further that by nucleic acid composition it is meant, a composition comprising a sequence of DNA having an open reading frame that encodes an Anthozoa chromo/fluoro polypeptide of the subject invention, i.e., an Anthozoa chromo/fluoroprotein gene, that is capable, under appropriate conditions, of being expressed as an Anthozoa chromo/fluoro protein according to the subject invention (Page 5, lines 19-24). WO 01/27150 teaches that in certain embodiments, the nucleic acids of the subject invention include one or more of the open reading frame encoding specific fluorescent proteins and polypeptides (Page 8, lines 21-23) and that the subject proteins fold rapidly following expression in host cell. WO 01/27150 also explains that by rapidly folding, it is meant that the proteins achieve their tertiary structure that gives rise to their chromo-or fluorescent quality in a short amount of time (Page 14-15, lines 37-2). WO 01/27150 further states, that also provided are nucleic acids that encode fusion proteins of subject proteins, which are fused to a second protein (Page 9, lines 26-27). WO 01/27150 discloses constructs comprising the subject

nucleic acid inserted into a vector, wherein such constructs can be used for a number of different applications, including protein production (Page 9, line 35); expression cassettes or systems can be used also for the synthesis and expression of subject proteins (Page 10, lines 12-15). Thus WO 01/27150 et al. teaches all the elements of **Claims 1-10 and 17-26** and these claims are anticipated under 35 USC 102(b).

Conclusion

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi

Robert B. Mondesi
12-15-04

Robert A. Wax
ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653